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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for use of the Renewal™ Acetabular Cup System.

Submitted By:	Orthopaedic Innovations, Inc.
Date:	January 2, 2002
Contact Person:	Gregory M. Mercuri Director of R & D
Proprietary Name:	Renewal™ Acetabular Cup System
Common Name:	Metal/Polymer Acetabular Components
Classification Name and Reference:	21 CFR 888.3358 Prosthesis, Hip, Semi-Constrained, metal/polymer, Uncemented – Class II
Device Product Code and Panel Code:	Orthopedics/87/LPH

DEVICE INFORMATION

Intended Use:

The Renewal™ Acetabular Cup System is intended for primary or revision reconstruction, with or without bone cement, of the acetabular portion of severely disabled and/or very painful hip joints, where radiographic evidence of sufficient sound bone is present. Clinical Indications for Use are:

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory joint disease (IJD), e.g., rheumatoid arthritis;
3. patients with failed previous surgery where pain, deformity, or dysfunction persists;
4. revision of previously failed hip arthroplasty; and
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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The Renewal™ Acetabular Cup System components are single use components intended for use in conjunction with associated metal or ceramic femoral heads as part of an uncemented or cemented total hip arthroplasty.

Device Description:

The Renewal™ Acetabular Cup System consists of metal acetabular shells and UHMWPE acetabular liners.

The Renewal™ Acetabular Shell will be available in a hemispherical titanium alloy shell with and without a 2 mm peripheral rim flare. The shells will be coated with commercially pure titanium porous beads.

Design features of the Renewal™ Acetabular shell are summarized below:

- Total hemispherical design
- Hemispherical design with a 2 mm peripheral flare
- Coated with CPTi porous beads
- No-Hole, 3-hole, 5-Hole, and 9-Hole options
- Threaded apical hole plug

The Renewal™ Acetabular Liners will be available with 0°, 10°, 15°, 20° overhangs with/without a 6+mm lateralized shift. The liner's internal geometry will be intended to be used with existing femoral heads manufactured from cobalt chrome or ceramic. The Renewal™ liner's external geometry will be designed to accept the Renewal™ Acetabular Shells.

Design features of the Renewal™ Acetabular Liner are summarized below:

- 360° liner overhang positioning options
- Features an easy-to-assemble snap lock system to lock the liner into the shell
- The lip of the 10° and 20° liners will be full hemispheres
- The lip of the 15° liner will be machined to 180°
- The liners will be offered with 0°, 10°, 15°, and 20° overhangs
- The 0° and 10° liners will also be offered with a 6+mm lateralized shift
- Internal diameter will have a 2mm chamfer to minimize impingement.

The thinnest part of any UHMWPE articulating insert will be greater than 4mm if attached to a metal backing.

Substantial Equivalence Information:

The intended use, material, type of interface, and design features of the Renewal™ Acetabular Cup System are substantially equivalent to the competitive devices previously cleared for market. The safety and effectiveness of the Renewal™ Acetabular Cup System are adequately supported by the substantial equivalence information, materials data, and testing results provided within the Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 5 2002

Mr. Gregory M. Mercuri
Director of Research & Development
Orthopaedic Innovations, Inc.
6188 Olson Memorial Highway
Golden Valley, Minnesota 55422

Re: K020145
Trade Name: Renewal™ Acetabular Cup System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: January 10, 2002
Received: January 16, 2002

Dear Mr. Mercuri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Renewal™ Acetabular Cup System

The Renewal™ Acetabular Cup System is intended for primary or revision reconstruction, with or without bone cement, of the acetabular portion of severely disabled and/or very painful hip joints, where radiographic evidence of sufficient sound bone is present. Clinical Indications for Use are:

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5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milleron

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020145

Prescription Use X OR Over-The-Counter Use_____